

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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	SYSTEM AND METHOD FOR	Group Art
Title:	ASSESSING HEALTHCARE RISKS	Unit: 3626

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPEAL BRIEF

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(i) REAL PARTY IN INTEREST

The present application has been assigned to Ingenix, a Delaware corporation.

(ii) RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to the present case.

(iii) STATUS OF CLAIMS

Claims 1-10 are pending, and claim 1-10 are herein appealed. Claims 1-10 stand rejected under 35 U.S.C. § 103 (a) over Robertson (U.S. Patent Application Pub. No. 2004/0024620) in view of Bienvenu (2002/0188476).

(iv) STATUS OF AMENDMENTS

No claim amendments were filed subsequent to the final rejection.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is generally directed towards a method for assessing the risk of insuring a healthcare patient in which a combination of demographic data (such as age and gender) and prescription data (for each prescription filled by the patient) are collected and analyzed to obtain a risk score for the patient (claim 1). An information processing system comprising computer-readable instructions that performs the same method is also claimed (claim 10).

The claimed invention does not merely describe collecting demographic data and prescription data. Instead, the claimed invention recites a detailed process in which: the prescription data for each prescription is assigned to at least one risk group based upon at least one medical condition typically treated by the prescription; risk data including the risk groups for all of the patient's prescription data is stored; and a risk score is calculated for the patient based upon the patient's risk data and demographic data. By analyzing the nature and mix of demographic data and prescription data related to a patient as recited in claims 1-10, a pharmacy-based clinical profile for a patient can be generated and serve as a marker of a patient's prospective health risk. See, e.g., specification at page 3.

Independent claims 1 and 10 are supported by the accompanying specification as follows. The claims recite "receiving demographic data on a patient and prescription data for each prescription filled by the patient" (*see, e.g.*, page 3, lines 11-13; Fig. 1, first oval), "assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription" (*see, e.g.*, page 4, lines 1-3 and page 6, line 8 to page 7, line 19; Fig. 1, step 104), "storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient" (*see, e.g.*, page 3, lines 8-9 and page 6 lines 1-5), and "calculating a risk score for the patient based upon the risk data and the demographic data of the patient." (*see, e.g.*, page 4, lines 11-13; page 8, line 10 to page 9 line 6; and page 10, line 14 to page 11 line 16; Fig. 1, step 112; and Fig. 4).

(vi) GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-10 are unpatentable under 35 U.S.C. § 103 (a) over Robertson (U.S. Patent Application Pub. No. 2004/0024620) in view of Bienvenu (U.S. Patent Application Pub. No. 2002/0188476).

(vii) ARGUMENT

(A) PRELIMINARY STATEMENT

Appellants respectfully submit that the Examiner has not established a *prima facie* case of obviousness as to claims 1-10 because the combination of references relied on by the Examiner is improper. The primary reference (Robertson) relates to automobile insurance risk assessment based upon a psychological questionnaire provide to applicants. It does not address health insurance risk assessment or prescription data and expressly rejects the use of demographic data for risk assessment. The secondary reference (Bienvenu) describes a system for collecting prescription data but does not describe any analysis of the data after it is collected. Given the teachings of these two references, it would not have been obvious for a person of ordinary skill in the art to combine these references to achieve all aspects of the invention recited in claims 1-10.

Moreover, even assuming it is proper to combine the references, the combination does not teach or suggest all the claim limitations as required under 35 U.S.C. §103(a). As discussed in detail below, neither reference teaches or suggests any of these expressly recited features of claims 1-10: assigning prescription data to risk groups based upon a medical condition treated by the prescription, storing risk data including all risk groups for the patient's prescription data, or calculating a risk score for the patient based upon the patient's risk data and demographic data.

Accordingly, Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the Examiner's rejection of claim 1-10.

(B) DESCRIPTION OF THE APPLIED ART

Claims 1-10 stand rejected 35 U.S.C. § 103 (a) over Robertson (U.S. Patent Application Pub. No. 2004/0024620) in view of Bienvenu (2002/0188476).

Robertson describes an automobile insurance risk classification methodology in which a psychological questionnaire is provided to applicants for automobile insurance to enable risk classification of the applicants. The questionnaire is designed to measure behavioral variables relating to personality traits and other personality or psychological characteristics of the individual. Robertson rejects the use of demographic data for risk assessment, does not relate to

health insurance or prescriptions, and does not describe any risk assessment methodology in which past data is used to calculate future risk.

Bienvenu describes a prescription data collection system. In the Bienvenu system, prescription drug history data of a patient is requested by an insurance company and provided to the insurance company by one or more pharmacy benefit managers (PBMs). The prescription history of a patient provided by each PBM may then be integrated to provide an aggregate summary of the patient's prescription history that the insurance company may use for various purposes, which are not performed by the Bienvenu system. For example, Bienvenu suggests that the prescription data gathered using the disclosed prescription data collection system may be used to determine the "probability that the prescription indicates a particular condition" to "provide the insurer with the likelihood that the applicant or insured has each of the conditions indicated by the prescribed drug." See ¶ 0039. Bienvenu also suggests that the collected prescription data may be used to make "an informed decision about the insurance related risks" by accepting, rejecting or affecting the individual's insurance rating "depending on the information in the individual's prescription history" using "actuarial tables and formulas." See ¶ 0043. However, these are merely offered as suggestions for possible use of the data collected by the Bienvenu system. Bienvenu does not disclose any analysis of the data after it is collected.

(C) THE COMBINATION USED TO REJECT CLAIMS 1-10 IS IMPROPER

The combination of Robertson with Bienvenu is improper because (I) Robertson, the primary reference, explicitly teaches away from the claimed invention; and (II) there is not teaching, suggestion, motivation or reason to combine Robertson and Bienvenu.

(I) Robertson Explicitly Teaches Away from the Use of Demographic Data to Assess Risk in the Automotive Insurance Context

Independent claims 1 and 10 in the present application require, *inter alia*, "receiving demographic data on a patient and prescription data for each prescription filled by the patient," and "calculating a risk score for the patient based upon the risk data and the demographic data of the patient" "wherein the risk data includes the risk groups for all prescription data of the patient." "Demographic data" may include a patient's age, gender, and the patient's mix of prescription risk groups (spec. at 4). "Prescription data" may include National Drug Codes

("NDCs") recorded on pharmacy claims, which are assigned to defined prescription risk groups ("PRGs") (spec. at 3). Thus, the present invention as recited in claims 1 and 10 requires collection of both demographic data and prescription data and the use of both types of data to calculate a risk score that enables assessment of the risk of insuring a healthcare patient.

In contrast to the present invention as recited in claims 1 and 10, Robertson does not mention the use of prescription data in any context and explicitly teaches away from the claimed use of demographic data to assess risk in the context of automobile insurance risk assessment (the only type of risk assessment addressed in Robertson). Specifically, Robertson expressly rejects the use of demographic data in the context of automobile insurance risk assessment because demographic data produces inaccurate risk assessment in that context. See, e.g., Robertson at ¶¶ 27 and 53. Robertson instead teaches the use of psychological questionnaires that gather information about the personality traits of the individual, which provides a more accurate basis for risk assessment. See, e.g., Robertson at ¶¶ 9-10. Therefore, Robertson teaches away from the use of demographic data to assess risk as recited in claims 1 and 10.

The Examiner has asserted that Robertson does teach the collection of demographic data for use in classifying automobile insurance risk (see Advisory Action). However, Robertson expressly rejects conventional "secondary characteristics" including age and gender as "crude" and "inefficient" indicators of automobile insurance risk. Robertson at ¶ 27. In fact, the entire teaching of Robertson is directed to the use of a risk classification questionnaire that does *not* collect demographic data. See, e.g., Fig. 3 and ¶¶ 62 – 64. Rather, the risk classification questionnaire includes at least one, and preferably all, of four survey statements at ¶¶ 55 – 58 in order to classify the risk of prospective insured individuals. These survey statements include:

[¶ 55] "I don't find it particularly difficult to get along with loud mouthed, obnoxious people";

[¶ 56] "In comparison to others my age, I have a less than average chance of having a heart attack";

[¶ 57] "I usually think carefully before doing anything"; and

[¶ 58] "In comparison to others my age, I have less than average chance of being fired from a job."

The above survey statements do not collect demographic data from prospective insured individuals. Rather, the statements are psychological statements designed to classify risk based

on an answer of: “agree” or “disagree.” These survey responses in no way constitute demographic data as recited in claims 1 and 10. As a result, the automobile insurance risk classification methodology in Robertson is not based upon such characteristics, but is instead based upon the individual’s responses to specific statements (e.g., those presented in ¶¶55-58) that provide insight into the personality traits and characteristics of the individual. Therefore, Robertson neither teaches nor suggests the collection or use of demographic data in calculating risk, but in fact teaches away from the use of such information.

In the Advisory Action dated March 7, 2007, the “Examiner disagrees that Robertson teaches away from the use of demographic data. Robertson at pg. 2 para 32 clearly states that the methodology need NOT be a replacement for conventional technique but can be in COMBINATION therewith. Thus, ‘secondary characteristics’ such as age and gender, reads on ‘demographic data.’” However, the Examiner’s conclusion is not supported by Robertson for two reasons.

First, Robertson clearly rejects the use of conventional, demographics’ based risk assessment in the auto insurance context. In the paragraph immediately following the statement cited by the Examiner in ¶32, Robertson states:

“In one embodiment, the selection of the particular personality traits is made so as to produce a statistically significant greater prediction of insurance loss than that associated with only the conventional variables.” Robertson at ¶33.

Moreover, the only “combination” of the methodology with “conventional variables” described in Robertson is possible analysis that maybe performed after auto risk has been assessed or classified using the survey responses described above. Specifically, once a prospective insured has been risk classified according to steps 300, 302 and 304, *i.e.*, steps not involving collection of conventional variables, the results of the risk classified individual may be combined with traditional methodologies. Specifically, Robertson states that “[o]nce the prospective insured has been classified into a particular risk group, standard underwriting techniques are applied to determine the cost of the risk group, and hence, an appropriate insurance rate to charge the prospective insured.” Robertson at ¶ 64. Therefore, contrary to the Examiner’s assertion, Robertson does not teach or suggest calculation of a risk score using demographic data for risk assessment. Moreover, Robertson’s specification makes clear that the Examiner is interpreting the sentence too broadly. Based upon the description above, it is clear

that Robertson does not teach the use of conventional variables in its risk assessment methodology.

Second, to the extent that Robertson discusses use of demographic data, it is for devising a questionnaire and not for risk classification, which is the subject of the pending claims. Robertson distinguishes between a methodology for devising the questionnaire and a methodology for risk classification. Figs. 1, 2(a) and 2(b) and corresponding ¶¶ 35 – 61 relate to “a methodology for *devising* the questionnaire,” ¶ 35, which involves administering a survey, and collecting and analyzing survey data, ¶ 51-61. Such methodology is not classifying risk. Rather, after survey statements are administered, they are analyzed to determine whether the statements may subsequently be useful in a risk classification questionnaire. Robertson acknowledges that in administering the survey, conventional classification variables were gathered from the survey participants, ¶ 51, but, in terms of risk classification, states at ¶ 53 that “the use of conventional variables has been found to be a fairly crude and inefficient predictor of claim reporting.” The survey aspect of Robertson is separate from the risk classification questionnaire aspects in Robertson, and the risk classification questionnaire for classifying risk of a prospective insured does not use conventional variables.

(II) There is No Motivation to Combine Robertson and Bienvenu

The PTO has the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. MPEP § 2142 (“The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.”) “Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.” *Ecolchem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000) (citations omitted). More recently, the U.S. Supreme Court indicated:

When it first established the requirement of demonstrating a teaching, suggestion, or motivation to combine known elements in order to show that the combination is obvious, the Court of Customs and Patent Appeals captured a helpful insight. . . . a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to

look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

KSR Int'l Co. v. Teleflex, Inc., 127 S.Ct 1727, 1741 (2007). Therefore, the PTO should show at least that some objective teaching or suggestion in the prior art or knowledge generally held by one of ordinary skill would lead an individual to modify the relevant teachings of a reference *or* should identify a reason that would have prompted a person of skill in the field to combine the elements in the way claimed. *Id.* For purposes of obviousness, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). The PTO should provide “an apparent reason to combine the known elements in the fashion claimed” and “this analysis should be made explicit.” *KSR*, 127 S.Ct. at 1741. Therefore, the combination of Robertson and Bienvenu is insufficient to establish obviousness absent some teaching, suggestion, motivation or reason to do so in the references themselves or in the knowledge of one of skill in the art.

The Examiner argues that “[i]t would have been obvious to add this feature [of “screening prescription history of an insurance applicant”] to the Robertson method with the motivation of having an effective system and method for assessing prescription drug history information stored in the databases, processing the information and incorporating the information in the insurance process (Bienvenu; Pg. 1, Para. 7).” *Office Action* of November 28, 2006, at page 3.

The Examiner’s statement is made only with the benefit of hindsight. Robertson teaches a fundamentally different methodology (character trait based risk assessment) in a different context (automobile insurance). Robertson has nothing to do with healthcare, patients, or prescription data, does not disclose or allude to any form of risk assessment relating to prescription data, and rejects the use of demographic data.

Additionally, Robertson does not teach or suggest any risk assessment methodology based upon prior activities of the insured individual. The Robertson auto risk assessment methodology is based upon character trait assessment of the individual, and apparently not on past activities (such as auto accidents) because “a tendency to report (or fail to report) an

accident can also be influenced by an individual's personality traits, as well as by various aspects of the individual's character, such as honesty, morality, etc. (collectively 'character traits')." Robertson at ¶ 0034. Robertson therefore teaches drafting of "a survey ... with about 50 individual items that tap into personality traits that may affect accident involvement and reporting." Robertson at ¶ 0035. Thus, Robertson teaches risk assessment based upon assessment of character traits, not past data.

In contrast, in the present invention as described in claims 1-10, prescription data for each prescription prescribed for or filled by the patient is used to create risk data for the patient. Thus, past prescription activities of the patient are used in combination with demographic data in the risk analysis calculation. This further illustrates the fundamental difference between the claimed methodology and that described in Robertson.

Given the teaching of Robertson, one of ordinary skill would not have been prompted to combine Robertson with Bienvenu to achieve the claimed invention. Bienvenu teaches a system for collecting and storing prescription data. Bienvenu has nothing to do with auto insurance risk assessment (the subject of Robertson), does not teach or suggest the collection of demographic data, and does not disclose any method for assessing health insurance risks, much less the claimed method of assessing health insurance risk using a combination of demographic data and prescription data. The reference makes a general allusion to the possibility of using prescription data collected by the disclosed system for a number of purposes, including risk assessment (Bienvenu at ¶ 43), but this does not constitute a teaching of any such method. Nor does it teach or suggest a risk assessment method using the claimed combination of demographic data and prescription data.

In rejecting the claims using the combination of Robertson and Bienvenu, the Examiner has apparently premised his rejection on an unsupported assumption that all types of insurance risk assessment are analogous. In other words, the Examiner assumes that patient healthcare risk assessment factors and methodologies are analogous to those used in automobile insurance risk assessment. This premise is nowhere supported in the art of record. In fact, as discussed above, Robertson itself establishes that the methodologies are different. Robertson's auto risk assessment methodology is based on character trait assessment, and not on past activities.

Moreover, it makes no sense to assume that, presented with a patent on automobile insurance risk calculation based upon a psychological survey and another patent on a system for

collecting prescription data, one of ordinary skill in the art would find it obvious to combine the two references to achieve the claimed invention in which health insurance risk is assessed based upon both demographics data and prescription data. Therefore, the asserted combination fails the test for obviousness articulated by the Supreme Court in *KSR*.

(D) THE SUGGESTED COMBINATION DOES NOT DISCLOSE THE PRESENT INVENTION AS CLAIMED IN THE INDEPENDENT CLAIMS

Even if it were proper to combine the cited references, the combination of Robertson and Bienvenu does not disclose the present invention as claimed in the independent claims. Independent claims 1 and 10 of the present application include the following features: (1) assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription; (2) storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient; and (3) calculating a risk score for the patient based upon the risk data and the demographic data of the patient.

The combination of Robertson and Bienvenu does not teach or suggest all of the features recited in claims 1 and 10. The Examiner acknowledges that Robertson does not disclose using prescription data for a patient. *Office Action* of December 28, 2006, page 3, line 1. In addition, for the reasons discussed below, the asserted combination of references does not teach or suggest the claimed invention as recited in claims 1-10.

(1) assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription;

Neither Robertson nor Bienvenu teaches or suggests this feature. Robertson in no way describes or suggests the assignment of prescription data to one or more risk groups based upon medical conditions typically treated by the prescription. As discussed above, Robertson teaches an automobile insurance risk assessment methodology using a questionnaire to assess personality traits of the individual.

The paragraph in Robertson (¶64) describes assigning risk groups for automobile insurance applicants based upon their responses to one or more of the questions listed in ¶¶55-58 of the Robertson disclosure. However, claims 1 and 10 do not merely recite the assignment of risk groups, but instead require assignment of prescription data or each prescription to at least one risk group based upon the medical condition(s) typically treated by the prescription. Robertson does not teach or suggest any such feature.

Moreover, Bienvenu also does not teach or suggest the recited assignment of prescription data for each prescription to one or more risk categories based upon the medical condition(s) typically treated by the prescription. Instead, Bienvenu teaches the collection of prescription data for an individual from a plurality of PBM databases. Once collected, the system may determine category information and drug indication information for each drug (see ¶¶38 and 42 and Fig. 5, nos. 84 (drug classifications) and 88 (drug indications)). Neither of these is a risk category, nor is described as a risk category in Bienvenu. The Bienvenu system may also determine the probability that the prescription indicates a particular condition. See ¶39. Bienvenu also states that “expert rule systems may be incorporated within the system for providing mortality information based on the prescription drug history information.” ¶39. However, no further explanation or disclosure of these concepts is provided. Therefore, even assuming the description alludes to some sort of risk assessment based upon all prescriptions for an individual, the description does not teach, suggest or enable the assignment of prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription as recited in claims 1 and 10. In fact, the risk assessment process in Bienvenu is performed by insurers, having received the collected prescription information, using conventional actuarial tables and formulas as would be known to those of ordinary skill in the art. See ¶43. No further description of the risk assessment process is provided in Bienvenu.

Consequently, neither Robertson, nor Bienvenu, nor the asserted combination of the two references teaches or suggests the assignment feature recited in claims 1 and 10.

(2) storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient;

As discussed above, Robertson does not teach or suggest the generation or storing of risk data for a patient including risk groups for all prescription data of the patient. Instead, Robertson teaches generation of automobile risk assessment groups based upon an individual's responses to questionnaire questions that assess personality traits of the individual.

Moreover, while Bienvenu generally refers to risk assessment based upon prescription data (see ¶ 43), it provides no details concerning this process. Therefore, Bienvenu does not teach or suggest the generation of risk data including the risk groups for all prescription data of the patient as expressly recited in claims 1 and 10.

For at least these reasons, neither Robertson, nor Bienvenu, nor the asserted combination of the two references teaches or suggests the storing feature recited in claims 1 and 10.

(3) calculating a risk score for the patient based upon the risk data and the demographic data of the patient.

As discussed above, Robertson does not teach or suggest the generation or storing of risk data for a patient including risk groups for all prescription data of the patient. Instead, Robertson teaches generation of automobile risk assessment groups based upon an individual's responses to questionnaire questions that assess personality traits of the individual. Therefore, Robertson also does not teach or suggest the claimed feature of calculating a risk score based upon the risk data and demographic data of the patient. In fact, Robertson teaches away from the use of demographic and other types of collectable incident-based information in favor of questionnaire responses concerning personality traits as a more accurate risk assessment method.

Also, while Bienvenu generally refers to risk assessment based upon prescription data (see ¶ 43), it provides no details concerning this process. Therefore, Bienvenu does not teach or suggest the calculation of a risk score based upon the risk data and demographic data of the patient as expressly recited in claims 1 and 10.

For at least these reasons, neither Robertson, nor Bienvenu, nor the asserted combination of the two references teaches or suggests the calculating feature recited in claims 1 and 10.

Pending claims 2-9 depend from claim 1 and are believed to be patentable over the asserted combination of references for at least those reasons set forth above with reference to claim 1.

(E) CONCLUSION

For the reasons set forth above, Appellants respectfully request reversal of the Examiner's rejection of claims 1-10 under 35 U.S.C. § 103(a).

Should any additional fees be necessary, the Commissioner is hereby authorized to charge any fee deficiency associated with this paper or request to Deposit Account No. 04-1420.

Respectfully submitted,

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(viii) CLAIMS APPENDIX

We claim:

1. A method for assessing risk of insuring a healthcare patient, the method comprising:
receiving demographic data on a patient and prescription data for each prescription filled by the patient;
assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription;
storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient; and
calculating a risk score for the patient based upon the risk data and the demographic data of the patient.
2. The method of claim 1, wherein the step of assigning the prescription data to at least one risk group comprises using national drug codes to classify each prescription.
3. The method of claim 2, wherein the step of assigning the prescription data to at least one risk group further comprises categorizing each national drug code classification into one of a number of pharmacy risk groups.
4. The method of claim 1, further comprising defining additional member risk markers based on patient age and other characteristics known to indicate that the patient belongs to a high risk category and using the additional member risk markers to calculate the patient's risk score.
5. The method of claim 1, further comprising providing a clinical and demographic risk profile for the patient based on the patient's age, gender and a mix of clinical and demographic risk profiles and using the patient's clinical and demographic risk profile to calculate the patient's risk score.
6. The method of claim 5, further comprising providing multiple patient risk markers for patients with pharmacy services that indicate multiple medical conditions.

7. The method of claim 1, wherein each risk group is assigned a numerical risk value based upon the patient's demographic data, and the patient's risk score is the sum of the numerical risk values of the risk groups in the patient's risk data.
8. The method of claim 7, wherein the risk score is computed using pre-determined weights and a patient's patient risk marker profile.
9. The method of claim 3, wherein the pharmacy risk groups comprise patient risk markers.
10. An information processing system comprising computer-readable instructions for:
 - receiving demographic data on a patient and prescription data for each prescription prescribed for the patient;
 - assigning the prescription data for each prescription to at least one risk group based upon at least one medical condition typically treated by the prescription;
 - storing risk data for the patient, wherein the risk data includes the risk groups for all prescription data of the patient; and
 - calculating a risk score for the patient based upon the risk data and the demographic data of the patient.

(ix) EVIDENCE APPENDIX

None.

(x) RELATED PROCEEDINGS APPENDIX

None.